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Dated: August 6, 2004 Signature: _____

LILIA OLSEN

Docket: 554792000500

Docket No.: 554792000500
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re Patent Application of:
Gregory N. BEATCH et al.

Application No.: 09/913,373

Group Art Unit: 1626

Filed: January 28, 2002

Examiner: S. Wright

For: CYCLOALKYL AMINE COMPOUNDS AND
USES THEREOF

**PETITION REQUESTING
WITHDRAWAL OF LACK OF
UNITY OF INVENTION UNDER
37 CFR § 1.144**

MAIL STOP: RCE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is a petition to the Examiner's finding of lack of unity of invention. Applicants respectfully request withdrawal of the lack of unity, and associated objections, as provided for under 37 CFR §§ 1.499 and 1.144.

Summary of the Lack of Unity/Election Requirement

In a February 12, 2003 restriction/election requirement, the Examiner identified a subset of the compounds of claim 1 as allegedly not forming a general inventive concept under PCT Rule 13.1. On April 11, 2003, Applicants elected an embodiment and the associated group with traverse in order to be fully responsive to the requirement. In the Office Action dated May 7, 2003, the Examiner identified a subset of the compounds of claim 1 for examination with the elected

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embodiment and stated that the remaining subject matter of claims 1-85 is withdrawn from further consideration under 37 CFR § 1.142(b) as constituting other patentably distinct inventions. In the response dated November 13, 2003, Applicants set forth the reasons why the Examiner's determination of lack of unity was in error.

In the Office Action dated February 6, 2004, the Examiner further identified a subset of the compounds of claim 1 as not forming a general inventive concept under PCT Rule 13.1, and objected to the claims as containing non-elected subject matter. While admitting that the application of 37 CFR 1.142(b) is not appropriate, the Examiner improperly maintained the lack of unity under PCT Rules 13.1 and 13.2.

Unity of Invention

The subject application entered the US national phase as a section 371 filing from PCT application CA00/00117. As set forth in MPEP 1893.03(d), "Examiner's are reminded that unity of invention (not restriction) practice is applicable in... national phase applications submitted under 35 U.S.C. § 371." Thus, the claims in the current application must be reviewed under the unity of invention standards and not under restriction requirement standards.

Treatment of Unity of Invention for Markush Group Claims

In the May 7, 2003 Office action, the examiner sets forth a subset of claim 1 that he identifies for examination and requests amendment to limit claim 1 to the identified subject matter. Claim 1 is a Markush type claim. The correct standard for unity of invention for Markush type claims is set forth in MPEP 1850, subsection D, which states that

When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

- (A) All alternatives have a common property or activity;
and
- (B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

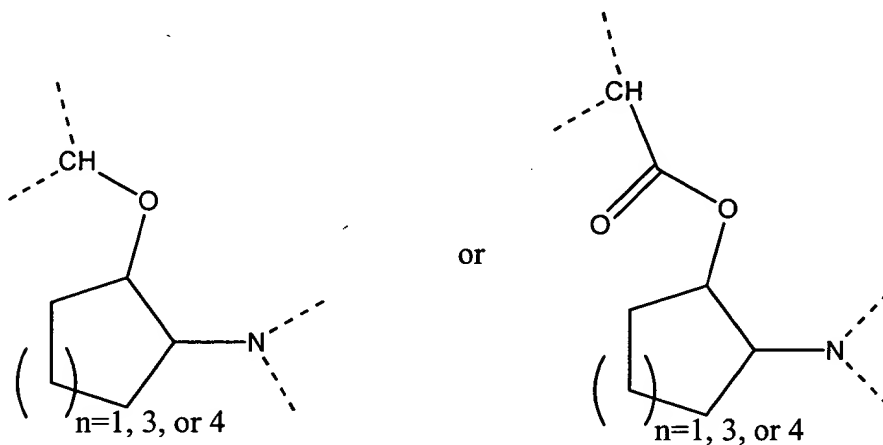
(C) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

Regarding the meaning of a “significant structural element” as used in section (B)(1) above, MPEP 1850, subsection D 1 states that this refers to two cases: (1) where the compounds share a common chemical structure which occupies a large portion of their structures, or (2) in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art.

Under the standard set forth above, a Markush claim possesses unity of invention unless the compounds within the Markush group either (1) do not share a common utility, or (2) do not share a significant common structural element or belong to a recognized class of chemical compounds.

(1) Common Utility: As described in the specification, the compounds of the Markush group set forth in claim 1 may be used in pharmaceutical compositions for the treatment of conditions including but not limited to arrhythmia. The compounds within the Markush group therefore share a common utility.

(2) Significant Structural Element: The compounds of the Markush group are all 2-amino cycloalkyl esters or ethers with a carbon bonded to the ether or ester group and with the cycloalkyl group being cyclopentyl, cycloheptyl or cyclooctyl. That is, all compounds in the group share the common structural element of



This molecular fragment is a significant structural element in the molecules set forth in the Markush group. The compounds share this structural element as a large portion of their structure.

Applicants also note that the PCT examiner, applying the above described standards for determination of unity of invention, did not reject claim 1 for lack of unity of invention.

The Compounds of Claim 1 are in Accordance with Unity of Invention Examples Provided by the MPEP.

Appendix AI, Annex B, Part 2 III of the MPEP sets forth examples of Markush claims for which unity of invention is present and is not present. The Markush group of pending claim 1 corresponds to examples provided by the MPEP that have a common structural feature. As in claim 1 of the present case, Examples 18-21 depict a series of compounds having a common central structure with various substituent groups. In addition, all the compounds have the same use. Because the examples correspond to the present claim 1, unity of invention is therefore present.

Moreover, the Markush group of claim 1 does not correspond to examples provided by the MPEP in which the exemplary compound lacks a common structural feature. Example 23 specifically depicts a Markush group of compounds having no common structure. The components of the Example 23 Markush group are inorganic salts, organic salts and carboxylic acids, amides, nitriles, phenols, amines, and heterocycles. Unlike Example 23, the Markush group of claim 1 in the present application includes substituents having common structural features such as those of Examples 18-21.

Applicants respectfully request that the Office point to any examples provided in the MPEP that support the Examiner's position.

Because the compounds in the claim 1 Markush group possess a common utility and share a significant common structural element, unity of invention is present.

Examiner's Arguments

In the Office Action dated February 6, 2004, the Examiner objected to claims 1-3 and 5-85 as containing non-elected subject matter. The Examiner addressed Applicant's arguments at page 7 of the Office Action. The Examiner states that "the compounds defined in the claims lack a significant structural element qualifying as the special technical feature that defines a contribution over the prior art." The Examiner asserts, without any basis in fact, that the core does not define a contribution over the art.

The Examiner has failed meet the requisite burden of establishing that the present compounds lack a common structural feature. In order to assert that the claims lack a special technical feature over the prior art, the Examiner must first establish that the compounds only have a small portion of their compounds in common. As discussed above, however, the compounds have the identified significant structural element as a large portion of their structure. As discussed above, the compounds in the claim 1 Markush group possess a significant structural element.

In addition, the Examiner continues to apply a partially incorrect standard for finding a lack of unity. Specifically, the Examiner asserts that "not to restrict the claims would impose a

burden on the examination of this application.” The burden of examination, while a possible reason for a restriction requirement under restriction practice, is not a reason to determine a lack of unity.

Finally, the Examiner’s restricted groupings have no basis in unity of invention standard or examples provided by the MPEP. Instead, they are an incomplete and *ad hoc* compilation of groups without any clear basis for their grouping.

For any or all of these reasons, applicants respectfully request that the lack of unity requirement be reconsidered and withdrawn, and that examination on the merits of the application proceed with respect to all pending claims.

Withdrawal of Finality

The Examiner issued a final office action dated February 6, 2004. To be fully responsive to this Office Action, Applicants have filed an RCE and response to accompany the petition for lack of unity. Upon withdrawal of the lack of unity, Applicants respectfully request withdrawal of finality and full consideration of the pending claims, as well as remittance of the fee for filing the RCE.

Concluding Remarks

It is respectfully submitted that *no fee is due* with respect to this Petition, since it seeks to rectify an incorrect lack of unity rejection in contravention of the Office’s own guidelines. In the unlikely event that the Patent Office determines that a fee and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **(554792000500)**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Dated: August 5, 2004

Respectfully submitted,

By 

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